Exhibit K

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

UMB BANK, N.A., as Trustee,	)	
	)	
Plaintiff,	)	No. 1:15-CV-08725
	)	(GBD)(RWL)
vs.	)	
	)	
SANOFI,	)	
	)	
Defendant.	)	
----------	)	

VIDEOTAPED DEPOSITION OF DAVID E. SMOLIN
New York, New York
Wednesday, March 20, 2019

Reported by:
KRISTIN KOCH, RPR, RMR, CRR
JOB NO. 156494

diligence report, focused here on this -- on the chemistry manufacturing and control section.

Q. And so, in your experience, this work typically happens pre closing?

A. Well, certainly the due diligence does and -- and there is -- there is a risk assessment in its broadest form that's accompanying that overall due diligence report. Risks and opportunities and the like for -- the term that was always used was are there any show-stoppers.

Q. And is it your experience that in due diligence typically there is sort of a full awareness gained of all of the underlying issues at the company?

A. It's difficult to get a complete awareness, but I -- I believe, having done this a number of times on behalf of Bristol-Myers Squibb, that we had quite a good understanding of what the issues were with respect to any given product.

Q. And in connection with any of your acquisitions or acquisition work while at

Q. Would it depend on what that information actually is?

A. Yes.

Q. Do you have any knowledge independent from what's set forth in the Phillips report about the specific micro -- microcarrier perfusion technology that was used with respect to the manufacture of Cerezyme and Fabrazyme?

A. No, I have not practiced perfusion technology, but I am knowledgeable about its purpose, but I am not an expert in perfusion technology.

Q. Have you ever had occasion to -- this may not be the right way to phrase it -- work with perfusion technology?

A. Yes.

Q. Okay. Can you describe that for me?

A. I previously referenced perfusion technology being applied for the inoculum expansion steps for the production of Enbrel.

Q. And anything other than that process in Enbrel?

A. No. Perfusion technology ordinarily

perspective, could provide an additional hurdle to over -- overcome with -- but I emphasize could provide an additional hurdle to overcome. The Consent Decree is meant to help assure the sponsor remains compliant in all respects with good manufacturing processes, otherwise the Consent Decree wouldn't have been issued in the -- in the first place.

So I would say it should be taken into account as to what the nature of the change is, the regulatory classification, and, if you will, offer a potential second check on that submission, but I don't see the Consent Decree as causing an undue delay in any submission of that type.

Q. But you have not yourself had personal experience submitting either a CBE-30 or CBE-0 in the context of a company operating under a Consent Decree; correct?

A. No, I have not.

Q. I think we briefly spoke about minor changes or at least you referenced the annual report changes and those are for minor changes; correct?

A. I don't recall specific discussions of these. They may have come up during the one meeting that we had here.

Q. But no specific recollection of discussing them otherwise?

A. No. I don't -- there is certainly no specific recollection regarding the technical information that supports them or the regulatory classifications that they might have been placed under.

Q. And with respect to the proposed process improvements that she references in her report, have you performed any analyses on your own to determine whether each would have been feasible to implement at the relevant time?

A. No, not -- not an analysis like that.

Q. Did you undertake any analysis with respect to the proposed process improvements that she references?

A. I only gave them consideration as to what they are proposed to be and how they may be implemented, what regulatory classification they may be given, based on what I knew about

too long, these improvements would not have made any difference, and I don't assume that to be correct, the regulatory classification.

Q. Right. But you can't affirmatively say that they are not accurate; correct?

MR. MINTZ: Objection to form.

A. To my knowledge, there was never a determination of what regulatory classification these process improvements would require.

Q. And you can't affirmatively state one way or the other today whether they would have been qualified as a CBE-0, a CBE-30 or some other classification; correct?

MR. MINTZ: Objection to form.

Misstates the record.

A. What I wrote in 69 stands, and in respect to that it can't be assumed that the Sanofi position was correct.

Q. I understand that's what you have said. My question is slightly different.

Are you able to say with certainty that any of the process improvements that Ms. Phillips talks about in her report would have been accepted as a CBE-0 or a CBE-30?

A. I can't say that with certainty, but I think there is an appropriate probability that they would have been accepted under a lower regulatory classification that should have been pursued by direct discussion with FDA, because, in my opinion, these don't constitute major changes.

Q. But you have not yourself submitted any CBE-0s or CBE-30s that you can recollect; correct?

MR. MINTZ: Objection to form.

Q. For post-approval changes.

A. We have discussed that. I don't --

MR. MINTZ: Same objection.

A. -- recall.

Q. You go on in 71 to talk about "deciding what regulatory approach to take with respect to implementing a change to the approved process for making a biologic is a matter of judgment and discretion." Do you see that?

A. Yes.

Q. And you go on to say it's "a balance of regulatory risk and benefit."